SOP: LARs, Children, and Guardians				
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1 PURPOSE

1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:

1.1.1 Legally Authorized Representative

1.1.2 Children

1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.

3.1.1 When research is conducted in New Hampshire state laws indicate that no one may consent on behalf of another person for experimental treatment unless the procedure is approved by the probate court or a health care facility is testing for the presence of an antibody or antigen to a human immunodeficiency virus in a research setting as described below:

3.1.1.1 NH RSA 137-J:5, V(d) indicates nothing under the advance directives chapter gives an agent under a healthcare power or a surrogate decision maker the authority to consent to an experimental treatment.

3.1.1.2 NH RSA 464-A:25(d) states that a guardian over the person does not have the authority to consent to experimental treatment unless the procedure is approved by the probate court.

3.1.1.3 NH RSA 141-F:5(III) states that a health care facility engaged in medical research may, without first obtaining consent to the testing, subject any body parts, fluids, or tissues to a test for the presence of an antibody or antigen to a human immunodeficiency virus in accordance with rules adopted by the commissioner under RSA 141-F:4 if the testing is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

3.1.2 For research outside New Hampshire, a determination of who is a Legally Authorized Representative is to be made with consultation from D-H legal counsel.

3.2 DHHS and FDA's Subpart D applies to all research involving children.

3.2.1 When research is conducted in New Hampshire all individuals under the age of 18 years are children. Contact D-H legal counsel for more information.

3.2.1.1 Exceptions exist under NH RSA 21-B:2 and B:3. Emancipated minors may consent to medical treatments and may consent to research. Contact D-H legal counsel for more information.

3.2.2 For research outside New Hampshire, a determination of who is a child is to be made with consultation from D-H legal counsel.

3.3 Unless the IRB has waived the requirement to obtain consent, when research involves non-emancipated children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care[1]. Before obtaining permission from an individual who is not a parent, contact D-H legal counsel.

4 RESPONSIBILITIES

[1] This is the DHHS and FDA definition of "guardian".

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102, 45 CFR §46.402

7.2 21 CFR §50.3